FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

September 1, 2009

8:00 a.m.	Call to Order Introduction of Committee	**S. Gail Eckhardt, M.D.** Chair, ODAC
	Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official, ODAC

The committee will discuss supplemental NDA (sNDA) 021-673/S-009, CLOLAR (clofarabine) Injection for intravenous use, Genzyme Corporation, proposed indication for the treatment of previously untreated adults aged 60 years or older with acute myeloid leukemia with at least one unfavorable baseline prognostic factor.

8:10 a.m.	Opening Remarks	**Richard Pazdur, M.D.** Director, Office of Oncology Drug Products (OODP), OND, CDER, FDA
8:15 a.m.	**Guest Speaker** Prognosis in Older Patients with Newly-Diagnosed Acute Myeloid Leukemia (AML)	**Elihu Estey, M.D**. Member Fred Hutchinson Cancer Research Center, Seattle Professor of Medicine, Division of Hematology University of Washington School of Medicine
8:40 a.m.	**Sponsor Presentation** Introduction	**Genzyme Corporation** **Mark Hayes, Ph.D.** Group Vice President, Regulatory Affairs Genzyme Corporation
	AML in Older Adults: A Defined Unmet Need	**Harry Erba, M.D., Ph.D.** Associate Professor, Internal Medicine University of Michigan
	Clinical Overview for Clolar in AML in Older Adults	**Michael Vasconcelles, M.D.** Group Vice President and Global Therapeutic Area Head, Transplant and Oncology Genzyme Corporation
	Key Issues for Consideration	**Michael Vasconcelles, M.D.**
9:20 a.m.	**FDA Presentation** Clolar for elderly AML	**sNDA 021-673/S-009** **Martin Cohen, MD** Medical Officer Division of Drug Oncology Products (DDOP), OODP, OND, CDER, FDA
10:00 a.m.	*Break*	
10:15 a.m.	Questions to the Presenters	
10:45 a.m.	Open Public Hearing	

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11:15 a.m. Questions to the ODAC and ODAC Discussion

12:15 p.m. *Lunch*

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1:10 p.m.	Call to Order Introduction of Committee	**S. Gail Eckhardt, M.D.** Chair, ODAC
	Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official, ODAC

The committee will discuss New Drug Application (NDA) 022-489, proposed trade name ONRIGIN (laromustine) Injection, Vion Pharmaceuticals, Inc., proposed indication for remission induction therapy for patients 60 years or older with de novo poor-risk acute myeloid leukemia (AML).

1:20 p.m.	Opening Remarks	**Richard Pazdur, M.D.** Director, Office of Oncology Drug Products (OODP), OND, CDER, FDA
1:25 p.m.	**Sponsor Presentation** Introduction	**Vion Pharmaceuticals, Inc.** **Tanya Lewis** Vice President, Regulatory & Quality Vion Pharmaceuticals, Inc.
	Treatment Challenges in AML	**Bob Löwenberg, M.D., Ph.D.** Chairman, Dept. of Hematology Erasmus University Medical Center, Rotterdam
	AML in the Elderly	**Alan Burnett, M.D.** Professor, Dept. of Hematology University of Wales College of Medicine, Cardiff
	Onrigin™ Clinical Experience: Efficacy & Safety	**Ann Cahill** Vice President, Clinical Affairs Vion Pharmaceuticals, Inc.
	Poor-risk AML in the Elderly	**Francis Giles, M.D.** Chief, Division of Hematology and Oncology University of Texas, San Antonio
	Benefit/Risk Considerations & Clinical Perspective	**Gary Schiller, M.D.** Professor, Dept. of Hematology/Oncology UCLA School of Medicine
	Closing Remarks	**Ann Cahill** Vice President, Clinical Affairs Vion Pharmaceuticals, Inc.

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2:05 p.m.	**FDA Presentation**	**NDA 022-489**
	Laromustine for Remission Induction in Patients 60 Years or Older With *De Novo* Poor-risk AML	**Albert Deisseroth, M.D.** Medical Officer Division of Drug Oncology Products (DDOP), OODP, OND, CDER, FDA
2:45 p.m.	*Break*	
3:00 p.m.	Questions to the Presenters	
3:30 p.m.	Open Public Hearing	
4:00 p.m.	Questions to the ODAC and ODAC Discussion	
5:00 p.m.	Adjourn	